

Remarks/Comments

Claims 1-5, 8 and 13 are pending in the present application.

Rejection for Obviousness-type Double Patenting

The currently claimed invention is rejected for obviousness-type double patenting in view of commonly owned U.S. Patent No. 6,245,740. The Office Action states that the reasons for this rejection were previously cited in prior Paper No. 7, Section 11, however, this is technically correct. The rejection cited in the prior Office Action was for double patenting, not obviousness-type double patenting. This is akin to changing a 102 anticipation rejection to a 103 obviousness rejection and saying they are the same. They are not. This new rejection was not necessitated by any amendment or information submitted in an IDS¹, thus, because the present rejection is new it was improper to impose a Final office action on the Applicants, and withdrawal of finality is requested.

However, in response to the new rejection under the judicially created doctrine of obviousness-type double patenting, the attorney for Applicants submits herewith a Terminal Disclaimer that meets the requirements set forth by the Office to overcome this provisional rejection.

To further clarify the record, Applicants address the comment in the prior Office Action that there "is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application, which matured into a patent." The patent being a reference to U.S. Patent No. 6,245,740. In fact, claims corresponding to the present claim were presented in the original filing that matured into the '740 patent.

The Examiner's attention is directed to the prosecution history of the '740 patent, specifically to Paper No. 10, page 2 where the prior Examiner insisted that the originally filed claims directed to either solutions or powders of G-CSF were not enabled. In that Office Action the Examiner insisted that a powder and solution had different properties and that only a powder was shown to work in claimed composition and methods in the working examples, therefore a solution was not enabled. In response, and merely to streamline prosecution in the face of what was considered an excessively stringent examination, the claims were narrowed to recite a powder and were subsequently allowed. The present application was filed with additional data to support claims to using a solution of G-CSF to create the claimed compositions and methods.

Now, the present Examiner asserts the present claims are subject to obviousness-type double patenting in light of the prior commonly owned patent because there is 'no scientific reasoning known to suggest that a solution prepared from a concentrated solution of G-CSF and neat polyol would have different properties than a solution

¹ M.P.E.P. 706.07(a) states: Finality is proper "...except where the examiner introduces a new ground of rejection that is neither necessitated by applicant's amendment of the claims nor based on information submitted in an information disclosure statement filed during the period set forth in 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p)."

prepared from powdered G-CSF and, for example, 75% glycerol", in clear contrast to the prior rejection in the examination of the '740 patent.

The present attorney for Applicants wholeheartedly agrees with the current Examiner and hopes that this brief sojourn clarifies the necessity for filing the claims of the present application.

As this rejection has now been rendered moot by the filing of a Terminal Disclaimer wherein it is stated that the '740 patent and a patent that may issue from the currently pending application will remain enforceable only while under common title, withdrawal of this rejection is requested.

Rejection under Section 112

Claims 1 and 8, and also their dependent claims, are rejected as vague and indefinite. In particular it is stated that the terms 'solution' and 'mixture' are used interchangeably and this creates indefiniteness as to what the physical form of G-CSF:glycerol is intended by the claims. It is also alleged that because there is no solvent cited that the solution of G-CSF is indefinite. The attorney for Applicants respectfully disagrees for the following reasons.

During prosecution, claims must be "given the broadest reasonable interpretation consistent with the specification" (M.P.E.P. 2111 and sections therein). Also, the broadest reasonable interpretation of the claims must also be consistent with the interpretation that those skilled in the art would reach. *In re Cortright*, 165 F.3d 1353, 1359, 49 USPQ2d 1464, 1468 (Fed. Cir. 1999).

The term solution is used in the specification and claims to denote a liquid that has a biologically active agent present in it that has been dissolved. This is entirely consistent with the dictionary definition, which is "the state of being dissolved". Thus, it should be abundantly clear from the ordinary meaning of these terms, that the starting material of G-CSF is a solution, namely, a liquid solution where the G-CSF is dissolved, and the mixing with the polyol must therefore also result in a solution. This is consistent with using the term mixture as described below.

The Examiner has correctly noted that some polyols may come in the form of a powder. For clarity, in this case the polyol would be dissolved in the solution of G-CSF and the form of the G-CSF: polyol mixture is a liquid solution. However, it is argued that this is clear from the current claim language, specification and surrounding discussion with the Office.

The term 'mixture' is used to show that there has been a combination of two or more ingredients, in one instance, a mixture of a liquid solution of G-CSF and a polyol. This is how the term is used in the specification and it is consistent with the ordinary meaning of the term. Indeed, the dictionary definition of the term mixture is "something produced by mixing" or "a composition of two or more substances that are not chemically combined with each other and are capable of being separated".² This definition merely states that the mixture is the combination of

² The American Heritage® Dictionary of the English Language, Fourth Edition Copyright © 2000 by Houghton Mifflin Company. Published by Houghton Mifflin Company. All rights reserved.

the two substances, which is consistent with mixing of two solutions, or of a solution, and a powder that can result in a solution.

Regarding the statement in the last response, page 7, last paragraph cited on page 4 of this Office Action, the term suspension is also consistent with the use of a liquid solution of G-CSF when mixed with glycerol. The dictionary definition of a suspension under 'chemistry,' is: "A system in which microscopically visible particles are dispersed throughout a less dense liquid or gas from which they are easily filtered but not easily settled because of system viscosity or molecular interactions." The ordinarily skilled artisan would understand that a liquid solution of G-CSF, as discussed above, could form a suspension when mixed with pure glycerol because glycerol has such a vastly higher degree of viscosity. However, for the sake of clarity, it should be stated that the G-CSF:glycerol may *resemble* a suspension depending on the degree of mixing, but is more properly considered a liquid solution.

Thus it is asserted by Applicants that the usage of the various terms in the claims and specification are not unclear and are consistent with their ordinary meaning such that one of skill in the art could understand the metes and bounds of the claims as written.

In addition, the claims allegedly lack definiteness for not citing a specific solvent. The fact that a solvent is not listed does not in any way hinder the definiteness of these claims because it is dogmatic in patent law that "that which is well known need not be taught and is preferably omitted" (*Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986)). The M.P.E.P. has stated that an applicant should direct claims to the nature of an invention, and not engage in listing each and every component that can or should be used if it is not part of what is inventive. The conciseness of citing only a solution as opposed to listing solvents is for clarity purposes and should in no way impinge the definiteness of the presently claimed invention.³ Furthermore, since G-CSF has been thoroughly studied and reported on in the scientific literature in various forms including dried solids and solutions, an artisan of ordinary skill would understand without undue complication or confusion what kind of solvents and conditions could be used to dissolve G-CSF. And just because there are many potential solvents for G-CSF does not mean that one of ordinary skill could not determine which solvents would be suitable for use in the present invention without undue experimentation.

It is respectfully submitted that the terms at issue are clear and the rejection and the request for clarification therein should be withdrawn.

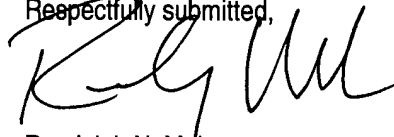
³ "...the definiteness of the language must be analyzed, not in a vacuum, but always in light of the teachings of the disclosure as it would be interpreted by one of ordinary skill in the art. ... **the applicant need not explicitly recite in the claims every feature of the invention.** For example, if an applicant indicates that the invention is a particular computer, the claims do not have to recite every element or feature of the computer. In fact, **it is preferable for claims to be drafted in a form that emphasizes what the applicant has invented** (i.e., what is new rather than old). *In re Dossel*, 115 F.3d 942, 946, 42 USPQ2d 1881, 1884 (Fed. Cir. 1997)." [emphasis supplied] M.P.E.P. 2106.V.A.2

Appl. No. 09/728,534
Amdt. dated September 5, 2003
Reply to Office action of March 6, 2003

CONCLUSION

It is submitted that the presently pending claims are now in form for allowance and allowance is earnestly requested. Should a telephone call help facilitate prosecution of this application; the Examiner is encouraged to telephone the undersigned attorney at the number listed below.

Respectfully submitted,



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